



# BTL-3000

**SERIES OF WHOLE-BODY  
TUBS TYPE DELTA**

**USER'S MANUAL**

**CONTENTS:**

<b>1</b>	<b>INSTRUCTIONS FOR USE .....</b>	<b>3</b>
1.1	Outward Appearance .....	4
1.2	Equipment of Delta Tubs .....	4
1.3	Controls .....	5
1.4	First Start and Control.....	5
1.4.1	Underwater Massage by Hand Subaqual Jet.....	6
1.4.2	Control of Air-Massage System .....	6
1.4.3	Control of Hydromassage System .....	6
1.4.4	Carbonic Baths .....	6
1.5	Optional Supplementary Systems and Accessories.....	7
1.5.1	Disinfection .....	7
1.5.2	Light.....	7
1.5.3	Electric Heating.....	7
1.5.4	Filtration.....	7
1.5.5	Recycling .....	7
1.5.6	Steps .....	8
1.6	Maintenance and Cleaning .....	8
1.6.1	General Principles of Cleaning .....	8
1.6.2	Cleaning and Disinfection .....	8
1.6.3	Maintenance .....	9
1.7	Principles of Secure Handling .....	9
1.8	Indications.....	10
1.9	Counterindications .....	11
1.10	Terms of Guarantee.....	12
1.11	Acceptance Criteria.....	12
<b>2</b>	<b>TECHNICAL PARAMETERS.....</b>	<b>13</b>
2.1	Transport and Operating Conditions .....	14
2.2	Applicable Standards .....	14

## 1 INSTRUCTIONS FOR USE

**Delta 10** - serves exclusively for application of carbonic CO<sub>2</sub> baths.

**Delta 20** - serves for application of whole-body air-massage (pearl) baths.

**Delta 30** - serves for application of whole-body hydromassage (whirlpool) baths with manual underwater massage by subaqual jet.

**Delta 40** - serves for application of whole-body hydromassage (whirlpool) baths and air-massage (pearl) baths with settable intensity, with the possibility of hand underwater massage by a subaqual jet.

**Underwater massage** can be effectively used for whole-body therapeutic massage or massage of individual body parts. Massage is performed under water by a hose with a massage jet at the end. Therapeutic effect of this type of massage is based on simultaneous acting of mechanical and thermal effects. Combination of appropriate temperature of bath and water flow leads to release of the muscle tonus and to overall relaxation. The pressure of the water flow causes also reactive supply of muscular tissue with blood, using nervous and metabolic effects. Underwater massage is used in treatment of posttraumatic states, fractures, injuries of muscles and joints, in insufficient blood circulation in extremities, in ischial, spastic and weak paralysis and in treatment of obesity. Significant effects of this type of hydrotherapy manifest themselves also in overall physical recondition after large physical strain.

**Air-massage effect** is provided by pearl massage by a flow of compressed air from tiny jets at the bottom of the tub. Air bubbles rise through the bath and gently massage the skin and superficial subcutis by rubbing the body surface. This brings sedative effect which has beneficial influence on both mental and physical state of the patient because it releases him/her from pain and stress. Pearl bath is applied mostly in insomnia, neurosis and other neurological diseases, as well as in diseases of locomotive organs where again its hyperaemic effect is used.

**Hydromassage effect** is induced by water flow from large side jets or from microjets which are ergonomically located against the most stressed areas of the upper extremities. Hydromassage is very helpful in treatment of posttraumatic states and injuries. Hydromassage whirlpool bath is an irritation and tonisation procedure and it is also a part of therapeutic physical education. It is effective in elimination of edemas, improvement of mobility of joints and release of contractures. It brings maximum overall relaxation of organism and therefore is optimal for spas, sanatoria, remedial institutions, sporting facilities and resorts of all kinds.

**Carbonic bath** – is prepared by saturating of water under pressure by CO<sub>2</sub> in carbonating machines. The effect of the carbonic bath depends on the warmth of water and the quantity of CO<sub>2</sub> in water. The carbonic bath is hypothermic. Use water of a temperature between 34°C and 28°C, depending on the patient's state - the lower temperature is more effective. Absorbed CO<sub>2</sub> has reflectoric effect on the whole organism, especially on the cardiovascular organs, through the nervous system. In the places where the bath touches the skin there occurs active hyperaemia. The vasodilatation skin erythema starts in 45-60 seconds after dipping in the bath of the temperature of 33°C and in 2-3 minutes there occurs sharp ischaemic borderline. The number of dilated capillaries in the skin increases, dilatation of arterioles causes acceleration of the blood flow. The skin is well supplied with blood and the feeling of coldness is thus lower. The CO<sub>2</sub> bath is therefore subjectively perceived as agreeably warm. The carbonic bath considerably tones up the circulatory system both in the peripheral (vessels) and central (heart) parts.

## 1.1 OUTWARD APPEARANCE

Hydromassage tubs of the Delta series are made of progressive and high-quality materials and equipped with top equipment the technology of which predestines it for long-lasting and trouble-free operation.

Construction height of the acrylate skeleton of the tub and the height of the bottom 100 mm above the floor enables use of hoists and lifts for immobile patients and reduces stress of the medical staff that do not need to bend too much at treatment of the patients.

Depending on the type, the tubs are equipped by up to 2 motors (1 pump and 1 blower) which provide underwater massage, hydromassage and pearl massage with the needed pressure of the medium and with the possibility of setting the pressure of hydromassage or smooth variation of intensity of air massage.

Large enough and clearly organized control panel includes all needed controls which serve for secure and perfect operation of the whole hydromassage equipment. The tub is panelled by covering panels. The skeletons of tubs and control panels are supplied in various colours. The covering panels are supplied only in the standard white colour.

## 1.2 EQUIPMENT OF DELTA TUBS

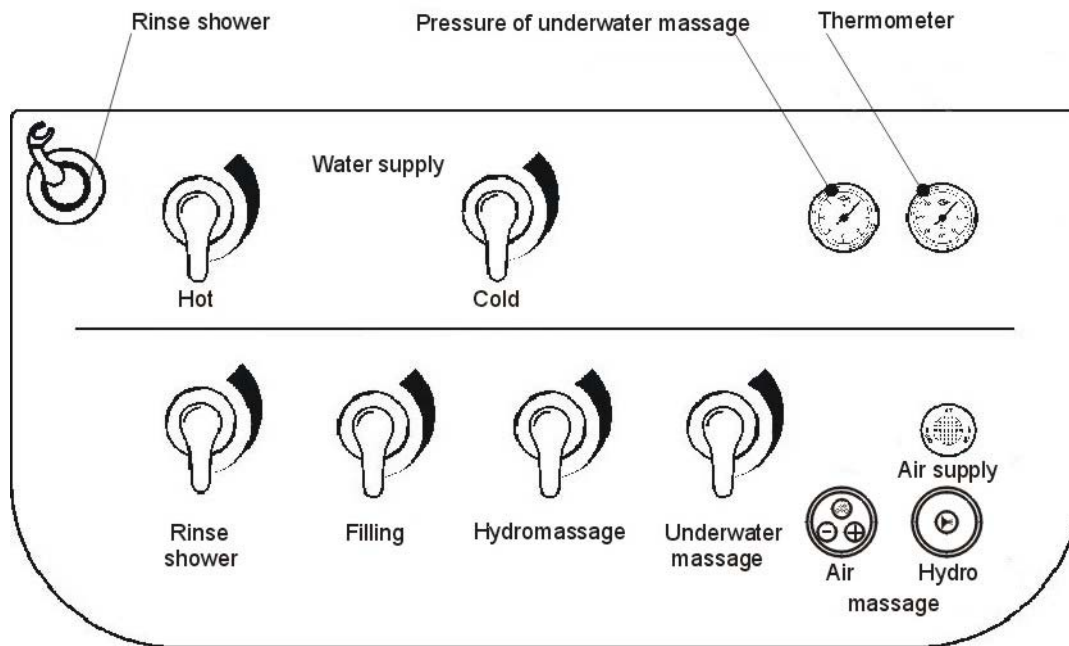
**Delta 10** - filling of cold, warm and CO<sub>2</sub> saturated water, thermometer.

**Delta 20** – air-massage system with the possibility of setting of intensity, 12 air-massage jets, thermometer for the supplied water.

**Delta 30** - subaqual jet with the possibility of smooth setting of water pressure, indicator of water pressure in the subaqual jet, thermometer, hydromassage system with 4 jets and 3 microjets.

**Delta 40** - subaqual jet with the possibility of smooth setting of water pressure, analogue indicator of water pressure in the subaqual jet, thermometer, air massage, setting of intensity of air massage, 12 air-massage jets, hydromassage with 4 jets and 3 microjets.

### 1.3 CONTROLS



The above displayed panel belongs to the Delta 40 tub. The control panels of types Delta 10-30 do not include some of the controls, depending on the tub type. The principle of control is the same for all types.

Control and operation are intuitive and very comfortable.

- Water supply – divided into cold and warm water. In addition, the filling is secured by a lever valve.
- Indicator of temperature of the supplied water.
- Indicator of water pressure in the subaqual jet.
- Subaqual jet – starting of the subaqual jet with the possibility of control of pressure.
- Rinse shower – valve for the rinse shower which is located in the upper left corner of the control panel and serves for rinse of the tub skeleton.
- Filling – to start water filling. (Tubs of type Delta 30 and 40 with recycling do not have this control element).
- Air massage - control of air massage (pearl bath) with the possibility of intensity control.
- Hydromassage – control of hydromassage (whirlpool).
- Air supply – air regulation enables to make air flow through the jets together with water.

### 1.4 FIRST START AND CONTROL

After successful installation disinfect the tub (follow the process described below) and rinse its interior by the hand shower. To start the hand shower open the respective valve on the control panel and press the small lever by the thumb.

Before supply of water set the required temperature by the two valves for warm and cold water and then open the "Filling" ball valve in the indicated direction. The tubs of types Delta 30 and 40, which are ready for connection of recycled water, do not have the "Filling" valve on the control panel. To start filling of water open the valves with cold and warm water. In such case the rinse shower is connected to the recycling system of water piping.

After filling the tub (the water top must be at least 2 cm above the highest microjet) select the sequence of hydrotherapy.

#### 1.4.1 UNDERWATER MESSAGE BY HAND SUBAQUAL JET

- Close the "Hydromassage" and "Subaqual jet" valves.
- Take the subaqual jet and immerse it in water.
- Press the "Hydromassage" button to start the pump.
- Slowly open the subaqual jet's valve and simultaneously check the water pressure on the manometer. For regulation of water pressure in the subaqual jet use the "Subaqual jet" valve.
- After achieving the needed pressure apply the underwater massage.
- To terminate the therapy close the "Subaqual jet" valve! Nonobservance of this process can cause a risk of injury of the therapist or the patient at next start of hydromassage!
- To switch off the pump press the "Hydromassage" button again.

**WARNING:**

- Always observe the correct process of termination of therapy, to ensure safety of the staff and the patient!
- If the "Hydromassage" and "Subaqual jet" valves are completely closed, do not let the pump run for more than 3 minutes. If there is not a minimum quantity of water flowing through the pump, there is a risk of its irreversible damage!

#### 1.4.2 CONTROL OF AIR - MESSAGE SYSTEM

- Press once the "AIR MESSAGE" button. The 12 jets on the bottom of the tub start flow air. After approx. 2 minutes the air gets warm which provides better and more comfortable massage.
- Second pressing of the same button activates variation of intensity.
- Third pressing of the same button switches air massage off.
- To decrease the intensity of air massage press the "-" (minus) button, to increase press the "+" (plus) button.

#### 1.4.3 CONTROL OF HYDROMASSAGE SYSTEM

- Completely close the "Subaqual jet" valve and open the "Hydromassage" valve.
- Press the "Hydromassage" button to start the pump.
- For control of pressure in the hydromassage system use the "Hydromassage" valve.
- To terminate the therapy close the "Hydromassage" valve and press again the "Hydromassage" button, or simply press the "Hydromassage" button.

**WARNING:**

- Always observe the correct process of termination of therapy, to ensure safety of the staff and the patient!
- If the "Hydromassage" and "Subaqual jet" valves are completely closed, do not let the pump run for more than 3 minutes. If there is not a minimum quantity of water flowing through the pump, there is a risk of its irreversible damage!

#### 1.4.4 CARBONIC BATHS

Carbonated water is let in by a special inlet (bottom filling) so that the saturation of the carbonated water does not decrease during filling.

First fill in warm (or even hot) water up to the suitable height and then top up by carbonated water.

**WARNING:**

- After filling the tub the water surface must be ventilated by a cloth, so that the patient cannot breath in CO<sub>2</sub> on the surface!
- During these baths the staff must increase their attention and check the patient!
- The rooms with these baths must be ventilated!

## 1.5 OPTIONAL SUPPLEMENTARY SYSTEMS AND ACCESSORIES

### 1.5.1 DISINFECTION

At the customer's request the tub can be equipped with the disinfection system. This system consists of the control button, vessel with inlet for the disinfectant and precise electronic dispenser.

After ending of the therapy press the disinfection button. The disinfectant is dispensed into the used water in the tub. Switch on all available systems (hydromassage and air massage) so that the disinfectant dissolves in water. Let the disinfectant act for the time stated by its producer. Disinfectants are listed in chapter 1.6.2 Cleaning and Disinfection.

After disinfection of the piping let water out and switch on air massage for 30 seconds so as to force water out of the air-massage system.

The pipes and hydromassage pumps are so designed that all water from these parts also runs out when draining the tub.

Follow the instructions in Chapter [Cleaning and Disinfection](#).

### 1.5.2 LIGHT

The tub can be equipped with a light to illuminate the patient and thus help the staff in orientation during the underwater massage.

### 1.5.3 ELECTRIC HEATING

At the customer's request the tub can be equipped with 3 kW electric heating. This heating is designed to heat water up only by several degrees, to keep it on the constant temperature which is optimum for therapy.

The acrylate skeleton that the tub is made of has excellent thermal-insulating properties which ensure long-lasting constancy of the water temperature. In case that water is filled in the tub for a long time, this heating enables to reach the required temperature.

At the customer's request the heating system can be set during installation to the required temperature which will be automatically kept by the thermostat. The heating is dependent on the operation of the hydromassage circuit – to start heating first switch on the hydromassage circuit.

### 1.5.4 FILTRATION

In some locations there occur problems with mechanical impurities which are released in the water mains. The best solution is to equip the main inlet to the building by the filter for mechanical impurities which must be designed accurately for the site (size of mechanical particles and maximum flow). If the filters cannot be installed on the inlets there should be a filter installed in the hydromassage circuit which will automatically filter water after switch-on of hydromassage.

It is necessary to check these filters periodically and change the filter cartridge when needed. The interval depends on the disposition and state of the water mains.

### 1.5.5 RECYCLING

When being manufactured the tubs can be adapted for connection to the system of water recycling. These tubs are equipped with special system for filling and draining of recycled water.

Recycling system usually consists of two recycling tanks where the used water is monitored and purified so as to comply with valid hygienic standards. Recycling is very demanding as for space and water piping, so it is necessary to take it into account already in the construction design.

**NOTICE:** If the tubs of types Delta 30 and 40 are prepared for the recycling system, the rinse shower is connected to recycled water and the tubs do not have the "Filling" ball valve.

## 1 . 5 . 6 S T E P S

With the tub there can be delivered steps for facilitation of access to and from the tub. The steps are designed to make the access to the tub manageable both for tall and small patients.

The steps consist of two stands with nonslip surface. They are made of aluminium which makes them stable as well as easily manipulable, especially thanks to low weight. The white glazed coating highlights their elegant design and enables trouble-free maintenance and disinfection.

The steps can be delivered without handrails or with the right or left one.

## 1 . 6 M A I N T E N A N C E A N D C L E A N I N G

### 1 . 6 . 1 G E N E R A L P R I N C I P L E S O F C L E A N I N G

Foreign substances (paint, putty, etc.) on the tub surface remove carefully, best by a wooden spattle. Never use **steel wool, metallic sponges, knives or scouring washcloth**. Stains of oil or grease can be removed by **denatured alcohol**.

Never use strong solvents such as **acetone, paint thinners, benzine, ammonia or chloride agents, or abrasive polish**.

For metallic parts use special **milk or paste**, like for polishing of a car. Finally wash the cleaned parts by warm water and disinfect them by disinfectants approved by the responsible health officer.

### 1 . 6 . 2 C L E A N I N G A N D D I S I N F E C T I O N

#### Regular cleaning after therapy

- After each therapy let water out by the red ball valve at the side of the tub, clean the tub by proper cleaner approved by the health officer (e.g. ChiroSan by Bochemie s.r.o.) and rinse it by the shower.
- In the hydromassage system the used water automatically runs out of the hoses (the hoses decline to the outlet). The outflow from the pump is provided by a drain.
- To force the used water out of the air-massage hoses let all air-massage circuits run for at least 30 seconds. Within this time all water is perfectly forced out of the piping.
- The equipment's parts which come into touch with the patient should be cleaned by agents approved by the responsible health officer.

#### Regular cleaning and disinfection of piping 4x per month

Since pollution by mineral sediments and scale considerably affects the activity of internal parts of the system (piping, pump), it is necessary to clean and disinfect the tub regularly.

- a) Fill the tub with warm water, like before bath.
- b) Pour in the water the exact manufacturer-recommended amount of disinfectant (e.g. Savagro by Bochemie s.r.o.).
- c) Run the system for approx. 10 – 15 minutes.
- d) Let water out.
- e) Fill the equipment with warm water and rinse the whole system.
- f) Run the system for approx. 10 – 15 minutes.
- g) Let water out.
- h) To force the used water out of the pipes let all pearl bath circuits run for at least 30 seconds.

#### Special cleaning in case of use of non-standard water

If the tub is operated in a place with non-standard water (very hard water, mineral water, etc.) it is necessary to clean it and rinse the hydromassage system at least once a week. The frequency of cleaning depends on quality of water (can be found out by water analysis). For sediments use special agents for dissolution. In case of neglect of proper maintenance and cleaning, complaints will not be accepted.



### 1.6.3 MAINTENANCE

The service inspection including check of all parameters of the equipment and possible service actions must be performed in intervals complying with the valid law, not longer than 36 months. The inspection is performed by the BTL authorized service department on the basis of the user's order. If the inspection is not done in the stated term the manufacturer does not guarantee the technical parameters and safe operation of the product.

### 1.7 PRINCIPLES OF SECURE HANDLING



This device has applied parts of type B.

The equipment does not use any medicaments or other substances which would be its integral part or would be applied by means of it.



- Before first switch-on of the equipment read carefully the User's Manual.
- The equipment must be professionally installed by an authorized representative of BTL.
- Installation and service instructions are not included in this Manual.
- All staff to use the equipment must be instructed of the way of operation, maintenance and checking of the equipment and of the safety principles.
- The electrical cabling which the equipment will be connected to must be installed and tested according to the existing valid standards (IEC 364). If you are not sure that the mains are completely OK get them inspected by an inspection engineer.
- Check if the parameters of the mains correspond to the requirements of the equipment according to Chapter 2
- The equipment is designed for work in the environment defined in Chapter 2. It must not be used in explosive environment. The equipment must not be used in connection with inflammable anaesthetics or oxidizing fluids (O<sub>2</sub>, N<sub>2</sub>O, etc.).
- Inspect the equipment thoroughly before each use (surface of the tub, functions of displays and controls, etc.); in case of any inconsistency stop using the equipment and contact the authorised service department. If the equipment's behaviour differs from the function described in this Manual stop using the equipment and contact the authorised BTL service department.
- If the equipment shows any defect or if you have doubts about its correct function, terminate the therapy immediately. If you do not determine the source of uncertainty after thorough study of the Manual, contact the authorised service department. If the equipment is used out of accord with this Manual or is used even if it shows functional differences from this Manual, the user is responsible for the damages caused by the equipment!
- Do not dismantle the equipment in any case, removal of protective covers implies the danger of electrical injury.
- All material and parts which come into direct contact with the patient's body must comply with the respective standards related to irritability, allergization, toxicity, genotoxicity and carcinogeneity (ISO 10993-1, ISO 10993-3, ISO 10993-5). The user is responsible for all these materials and parts if not supplied by the BTL equipment supplier.
- The equipment does not use or produce any toxic substances during its operation, storage or transport under the stated conditions.
- Before start of therapy check if all set parameters correspond to your intents.
- To terminate therapy press the respective control element, not the mains switch.
- The equipment and the accessories must not be used in a way out of accord with this User's Manual.
- At work with the equipment use the recommended protective tools.
- The equipment must be placed out of reach of children.
- Main switch use for:
  - switching on and off in operational breaks
  - at repairs and service
  - at weekend downtimes
  - in case of need of fast shut-down
- Do not add to the bath any liquid agents or powders, especially soaps, foams and oils, if not particularly designed for hydrotherapy systems.
- Do not leave persons with restriction in movements, mentally affected persons and children, unattended.
- Near the tub it is forbidden to use any portable electric device! Other electric devices in the room and their parts under voltage must be located and fixed so that they cannot fall into the bath!
- Put the tub into operation before the patient's entry – to prevent him/her from an unpleasant feeling at the first emission of water and air from the jets.
- Check the pressure of water in the subaqual jet. When underwater therapy runs at full power the water pressure can reach approx. 0.4Mpa, which is a value that could harm the patient in case of unprofessional handling.
- Do not start the equipment if the tub is not full of water, otherwise the water pump could be damaged.

- After filling up the tub all jets must be under water.
- Before starting of the motor check if there are not any undesired things such as cloth parts, sponges and anything that could be sucked into the pump, which would cause clogging of the pipe and reduction of power or even damage of the pump.
- The equipment contains components which could cause electromagnetic interference.
- It is recommended to separate the patients' rooms from the staff rooms so that the noise level in the staff rooms is reduced (unlike the patients, the staff is exposed to noise for approx. 8 hours a day). In addition it is suitable to divide the room (at least by curtains) to separate parts, one therapy and one patient each. In case of need extend the anti-noise measures.
- If after many years of operation it is necessary to discard the hydrotherapy equipment it is necessary to contact a specialized company dealing with this activity, or the supplier or manufacturer who will advise you on the process of liquidation, or to discard of it in a way which is usual for this type of devices. The equipment does not contain any toxic materials which could harm the environment in case of normal way of liquidation.

## 1.8 INDICATIONS

### **Underwater massage**

- Posttraumatic states in muscles and joints
- Post-poliomyelitis states
- Muscular atrophy
- Lumboischadic syndrome
- Arthrosis
- Bechterev's Disease
- Burger's Disease
- Myalgia

### **Air massage**

- Vasomotor neurosis, climacteric neurosis
- Insomnia
- Neurologic diseases
- Diseases of locomotive organs

### **Hydromassage**

- Post-operative states, states after injuries of locomotive organs
- Muscular atrophy
- Post-poliomyelitis states
- Peripheral paresis
- Trophic changes in extremities

### **Carbonic Bath**

#### **1. Heart and Circulatory Diseases**

- Essential, sclerotic and climacteric hypertension, angina pectoris
- Valvular defects, especially mitral insufficiency
- Heart defects after infectious diseases
- Some types of arrhythmia
- States after heart attack (9-12 month after occurrence)
- States after toxic heart damage

#### **2. Vascular Diseases**

- Peripheral vasoneurosis
- Atherosclerosis

- Functional vascular spasms

### 3. Nervous Diseases

- Encephalitis
- Parkinson's Disease
- Tabes dorsalis
- Vegetative Dystonia

## 1.9 COUNTERINDICATIONS

The list of contraindications is the list of cases in which the manufacturer does not recommend application of the selected therapy. Indeed the professionals who are aware of the possible consequences do not need to observe these listed contraindications – all responsibility for use of the therapy, however, lies with them.

### Underwater massage

- Acute inflammations
- Haemorrhagic diathesis
- Tumours in skin and subcutis
- Pregnancy
- States after heart attack, cardiovascular disorders
- Hypertension above 200/100mmHg
- Kidney diseases
- Varixes, post-thrombophlebitis states, states after ulcus cruris
- Active TB
- Allergy to therapeutic salts used in the bath
- Menstruation
- Skin wounds (including non-bleeding)
- Eczema

### Air massage

- Active TB
- Allergy to therapeutic salts used in the bath
- Menstruation
- Skin wounds (including non-bleeding)
- Eczema

### Hydromassage

- Active TB
- Allergy to therapeutic salts used in the bath
- Menstruation
- Skin wounds (including non-bleeding)
- Eczema

### Carbonic Bath

- Florid processes in heart and vessels
- Cardial decompensation
- Tachyarrhythmia
- Coronary sclerosis

- Proneness to collapse
- Anaemia and polyglobulia
- Hypotension
- Epilepsy
- Acute ictus
- Hysteria
- Active TB
- Menstruation
- Skin wounds (including non-bleeding)
- Eczema

#### 1.10 TERMS OF GUARANTEE

The manufacturer provides guarantee 24 months from the date of delivery of the hydromassage tub.

The guarantee expires if the equipment has been used out of accord with this Manual or in case of an unqualified intervention in the equipment. The guarantee does not apply to mechanical damage of the skeleton and panelling of the tub, neither to damage of the pump caused by incorrect handling (operation without water).

In case of any defect always contact the authorized BTL service department.

Installation of tubs must be done by qualified personnel with BTL accreditation. In case of "amateurish" installation the supplier does not guarantee for the installation part of the hydromassage equipment and the defects connected with unprofessional installation. Guarantee does not apply for these defects.

#### 1.11 ACCEPTANCE CRITERIA

When accepting the tub check if:

- the skeleton, frame and panelling of the hydrotherapy tub are not mechanically damaged and are completely OK
- the tub does not leak – there are no marks of water on the control panel and under the tub
- all hydrotherapy subsystems and their control are functioning and trouble-free

## 2 TECHNICAL PARAMETERS

Type	Delta 10	Delta 20	Delta 30	Delta 40
Material of the skeleton	Acrylate	Acrylate	Acrylate	Acrylate
Maximum volume of the tub [l]	300	300	300	300
Usable volume of the tub [l]	240	240	240	240
Time of filling [min]	3	3	3	3
Time of drainage [min]	4	4	4	4
Weight without water [kg]	120	130	135	145
<b>Underwater massage with water pressure indicator</b>	-	-	x	x
<b>Hydromassage system (whirlpool)</b>	-	-	x	x
Number of water jets	-	-	4	4
Number of microjets	-	-	3	3
Air-supply of hydromassage jets	-	-	x	x
<b>Air-massage system (pearl bath)</b>	-	x	-	x
Number of air-massage jets	-	12	-	12
Regulation of intensity	-	x	-	x
Air-massage system with intensity variation (pulsation)	-	x	-	x
Rinse shower	x	x	x	x
<b>Optional systems and accessories</b>				
Disinfection	-	o	o	o
Heating 3kW	-	o	o	o
Filtration	-	o	o	o
Preparation for connection to recycled water	-	o	o	o
Supply of carbonated water	x	-	-	-
Steps	o	o	o	o
<b>Power supply</b>				
maximum input	-	800VA	1600VA	2450VA
mains voltage ~ 198 V to 252 V (230 V nominal), alternating	-	Yes	Yes	Yes
frequency 50 Hz	-	Yes	Yes	Yes
protection class I (according to IEC 536)	Yes	Yes	Yes	Yes
<b>Internal chemical sources</b>	No	No	No	No
<b>Classification</b>				
applied parts of type	B	B	B	B
class according to MDD 93/42/EEC	IIB	IIB	IIB	IIB

x – standard, o – optional, - no

## 2.1 TRANSPORT AND OPERATING CONDITIONS

**Identification** BTL-3000 Series System

### Operating conditions

ambient temperature	+ 10 °C to + 40 °C
relative humidity	30 % to 75 %
atmospheric pressure	700 hPa to 1060 hPa
position	on legs
type of operation	continuous

### Transport and storage conditions

ambient temperature	- 10 °C to + 55 °C
relative humidity	25 % to 85 %
atmospheric pressure	650 hPa to 1100 hPa
position	on legs
storage time	max. 1 year
other conditions	transport only in the supplied packaging

## 2.2 APPLICABLE STANDARDS

No.	Name	IEC, EN, ISO, MDD
1	Medical electrical equipment Part 1: General requirements for safety	IEC 601-1
2	Amendments to IEC 601-1	A2, A11 a A12
3	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility. Requirements and tests	IEC 601-1-2
4	Industrial, scientific and medical (ISM) radio-frequency equipment - Radio disturbance characteristics - Limits and methods of measurement	EN 55011
5	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 2: Electrostatic discharge immunity test - Basic EMC Publication	IEC 61000-4-2
6	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated, radio frequency, electromagnetic field immunity test	IEC 61000-4-3
7	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 4: Electrical fast transients/burst immunity test - Basic EMC Publication	IEC 61000-4-4
8	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 5: Surge immunity test	IEC 61000-4-5
9	Medical devices - Risk Analysis	EN 1441
10	Biological evaluation of medical devices - Part 1: Evaluation and testing	ISO 10 993-1
11	The Medical Devices Directive 93/42/EEC	MDD 93/42/EEC

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